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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,774	02/04/2004	Bjarne Due Larsen	50412/018003	3539
21559	7590	04/27/2009	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			TELLER, ROY R	
			ART UNIT	PAPER NUMBER
			1654	
			NOTIFICATION DATE	DELIVERY MODE
			04/27/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/772,774	<b>Applicant(s)</b> LARSEN ET AL.	
	<b>Examiner</b> ROY TELLER	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47,50,163 and 194 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47,50,163 and 194 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/5/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

This office action is in response to the amendment, received 2/5/09, in which applicant has amended claims 47, 50 and 163; added new claim 194; and cancelled claims 41 and 49.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 47, 50, 163 and 194 are under examination.

### ***Information Disclosure Statement***

The information disclosure statement, received 2/5/09, is acknowledged. A signed copy is enclosed hereto.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47, 50, 163 and 194 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a “written description” rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

*Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the “written description” inquiry, is *whatever is now claimed*” (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus, i.e., the genus of a compound of the formula representing a peptide sequence of instant claim 163 wherein the amino acid residues may be D- and or L- forms, and having the N-terminal at N\* and the C-terminal at C\* and being optionally cyclic via a covalent bond between N\* and C\*.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1),

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the court states “An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention”.

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* SEQ ID NO: 287 . The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species. The instant specification describes numerous L form amino acids of instant formula, but the instant specification gives little to no guidance for the retro form, all D form and retro all D form of the peptide sequence of the formula. In the instant case, the specification fails to provide sufficient descriptive information to be used in the claimed composition for the retro form, all D form and retro all D form of the peptide sequence of the formula.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the genus of a compound of the formula representing a peptide sequence wherein the amino acid residues may be D- and or L- forms, and having the N-terminal at N\* and the C-terminal at C\* and being optionally cyclic via a covalent bond between N\* and C\*. The instant specification describes experimental results for compound 2 (SEQ ID NO: 298), drawn to the allowed application, 09/792,286. Compound 2 is drawn to the formula Ac-D-Tyr-D-Pro-D-4Hyp-Gly-D-Ala-Gly-NH<sub>2</sub>. See, *i.e.*, pages 72, example 1, pages 87-88, examples 6 and 7. Elected instant SEQ ID NO: 287 (compound 36) is drawn to the formula cyclo(-Gly-Ala-Gly-Hyp-Pro-Tyr-Asn-), see, *i.e.*, page 84, compound 36. Experimental results

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are provided for compound 2 (SEQ ID NO: 298) only. One can not always expect the same results from 2 different peptides, as evidenced by their different sequences, in the absence of experimental evidence. Lazar et al. (Molecular & Cellular Biology, 1988, Vol. 8, pp-1247-1252) describes a mutation of aspartic acid 47 and leucine 48 results in different biological activities, see entire article.

In the instant case, the specification fails to provide sufficient descriptive information to be used in the claimed composition. The general knowledge and level of those skilled in the art does not supplement the omitted description because specific, not general, guidance is what is needed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would not reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus.

The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, first paragraph for the reasons set forth above.

Applicant’s arguments were carefully considered but were not found persuasive. Applicant contends that the instant specification describes the synthesis of many peptides falling within the peptide formula. However, the examiner contends that the present claim encompasses numerous species that are not further described.

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There is substantial variability among the species. The instant specification describes numerous L form amino acids of the instant formula but the instant specification gives little to no guidance for the retro form, all D form and retro all D form of the peptide sequence of the formula. In the instant case, the specification fails to provide sufficient descriptive information to be used in the claimed composition for the retro form, all D form and retro all D form of the peptide sequence of the formula. Applicant further contends that the instant specification fully describes the retro forms, all D forms and retro all D forms of the peptide of the formula. However, the examiner contends that one of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the genus of a compound of the formula representing a peptide sequence wherein the amino acid residues may be D- and or L- forms, and having the N-terminal at N\* and the C-terminal at C\* and being optionally cyclic via a covalent bond between N\* and C\*. The instant specification describes experimental results for compound 2 (SEQ ID NO: 298), drawn to the allowed application, 09/792,286. Compound 2 is drawn to the formula Ac-D-Tyr-D-Pro-D-4Hyp-Gly-D-Ala-Gly-NH<sub>2</sub>. See, i.e., pages 72, example 1, pages 87-88, examples 6 and 7. Elected instant SEQ ID NO: 287 (compound 36) is drawn to the formula cyclo(-Gly-Ala-Gly-Hyp-Pro-Tyr-Asn-), see, i.e., page 84, compound 36. Experimental results are provided for compound 2 (SEQ ID NO: 298) only. One can not always expect the same results from 2 different peptides, as evidenced by their different sequences, in the absence of experimental evidence. Lazar et al. (Molecular & Cellular Biology, 1988, Vol. 8, pp-1247-1252) describes a mutation of aspartic acid 47 and leucine 48 results in different biological activities, see entire article.

Applicant further contends that the claimed peptides are only limited by their structural

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characteristics, not by their function. However, the examiner contends that the cited prior art does show a correlation between structural characteristics and function, that structure and function are intertwined. Applicant further contends that the instant specification provides the structure of many peptides within the scope of instant claim 163, including retro, all D, and retro D compounds, thereby satisfying the written description requirement. However, the examiner contends that, as the chemical compounds are claimed by structure that one of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises the genus of a compound of the formula representing a peptide sequence wherein the amino acid residues may be D- and or L- forms, and having the N-terminal at N\* and the C-terminal at C\* and being optionally cyclic via a covalent bond between N\* and C\*. The variability among the species is greater than the disclosure in the instant specification.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT  
1654  
4/21/09

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655